



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/338,904 | 06/23/1999 | PETER C. JOHNSON | 99-40117-US | 1951 |

7590

06/11/2003

DANIEL H GOLUB
REED SMITH SHAW & MCCLAY LLP
2500 ONE LIBERTY PLACE
1650 MARKET STREET
PHILADELPHIA, PA 191037301

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

20

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/338,904

Applicant(s)

JOHNSON, PETER C.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/5/01, 8/31/01, 10/9/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 112-162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 112-162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,11,16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1631

DETAILED ACTION

Originally filed claims 1-111 were directed to a method of manufacturing engineered tissue. The originally filed claims included limitations to imaging tissue and evaluating the images to derive various indices representative of the imaged tissue. No restriction requirement was made. The amendment submitted 8/17/00 (Paper No. 6, amendment A) cancelled claims 18-28, 30-42, 44-102 and 105-111. No amendments were made to the remaining claims and no new claims were added. The amendment submitted 3/5/01 (Paper No. 10, amendment B) cancelled all remaining originally filed claims and added new claims 112-134. This amendment was held to be non-responsive (see Paper No. 12, mailed 6/4/01) and the newly presented claims were considered to be drawn to a non-elected invention because they were no longer directed to methods of manufacturing engineered tissue. On 8/31/01 applicant submitted a request for CPA (Paper No. 15) and included an amendment (amendment C). This response was filed timely in response to Paper No. 12. On 10/4/01 applicant submitted a request for reconsideration (Paper No. 18). This response was also filed timely to Paper No. 12.

Applicant's request for CPA (Paper No. 15) was improper as the instant application has a filing date of 14 August 2000 (the date the first CPA was filed) and thus the application is not eligible for CPA practice. Since prosecution in the application was not closed, the CPA request should have been processed as an improper RCE. This was not done. It is noted that a Notice of Improper Request for Continued Examination (RCE) does not set any time period for reply. The time period set forth in the last Office action continues to run. In this case it would be the time period that was set in Paper No. 12. The amendment (amendment C) submitted with Paper No.

Art Unit: 1631

15 and the request for reconsideration (Paper No. 18) were timely filed and are considered to be responsive.

Applicant is advised that the improper CPA request is deemed moot in view of these responsive amendments and examination will proceed accordingly.

Amendment C added new claims 112-140. As amendment B was entered and had already added new claims numbered 112-134, these claims (including dependencies) have been renumbered in accordance with 37 CFR 1.126. Claims 112-140 of amendment C have been renumbered as 135-162, respectively.

Claims 1-111 have been cancelled. Claims 112-162 are currently pending. Claims 135-156 appear to be exact duplicates of claims 112-134. Claims 158-161 are dependent upon cancelled claims 1-4, respectively.

Claims 112-132 and 135-154 are directed to methods for obtaining tissue information representative of a given tissue type.

Claims 133-134 and 155-156 are directed to methods for obtaining imaging information representative of a given tissue type.

Claims 157-161 are directed to methods for manufacturing engineered tissue.

Although the goal of each group of claims differs, the method steps of claims 112-132 and 135-154 as well as the method steps of claims 133-134 and 155-156 are largely included within the limitations of original claims 1-111. As such, no restriction requirement will be imposed on the claims at this time. New claims 157-161 are directed to the same invention as that originally claimed.

Art Unit: 1631

Information Disclosure Statement

The information disclosure statements submitted 10/2/00 (Paper No. 8), 4/18/01 (Paper No. 11), and 8/31/01 (Paper No. 16) are noted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 112-156 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 09/338,908 and 09/338,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the claims are directed to applying a plurality of imaging methods to a plurality of tissue specimens and to derive various structural and functional indices.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is reminded that both the 09/338,908 and 09/338,909 applications have been allowed although they have not yet issued.

Claim Rejections - 35 USC § 112

Claims 112-162 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Basis for new claims 112-134 was stated to be on pages 11-18 as well as throughout the specification. No basis is seen for the claims as presently written. No basis was pointed to for new claims 135-156 and none is apparent. Applicant is requested to point out basis for each claim with more particularity.

Claims 157-162 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 157-162 appear to correspond to originally filed claims 1-4 and 103, respectively. They are not enabled for reasons of record as set forth for claims 1-4 and 103.

Claims 157-161 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1631

Claims 157-161 are confusing in depending upon cancelled claims 1-4, respectively.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

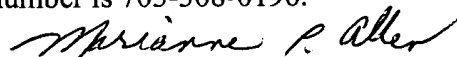
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

Application/Control Number: 09/338,904

Page 7

Art Unit: 1631

mpa

June 3, 2003